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(54) Title: DIETARY FIBER DELIVERY SYSTEM (57) Abstract A delivery system and method for delivering soluble dietary fibers in a chewable tablet form which is palatable and demonstrates a high degree of consumer acceptability.		

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Title: DIETARY FIBER DELIVERY SYSTEM

25 This application claims the benefit of Provisional Application No.
60/009,231 filed December 26, 1996

BACKGROUND OF THE INVENTION

30 1. Field of the Invention

The present invention relates generally to a delivery system for dietary fibers and more particularly to a delivery system for soluble dietary fiber supplements preferably in the form of a safe, chewable tablet, lozenge, wafer, cookie or the like which is comprised in part of a relatively low viscosity, non-
35 gelling and organoleptically pleasing dietary fiber component.

2. Description of the Prior Art

Unlike other nutrients, dietary fiber is not a single substance, but is a term used to identify plant polysaccharides and lignins that are not hydrolyzed by
40 the endogenous secretions of the human digestive system. Thus, they reach the colon intact. Plant components which make up dietary fiber include, among others: structural polysaccharides (cellulose and hemicellulose), nonstructural polysaccharides (pectines, B-glucans, gums and mucilages) and structural non-polysaccharides (lignin). Dietary fibers are commonly characterized by their
45 water solubility and their relative susceptibility to microbial degradation into fermentable and nonfermentable fiber fractions. In general, pectines, gums and mucilages are water soluble, while lignin, cellulose and hemicellulose are water insoluble.

Dietary fibers by definition reach the colon intact and thus generally escape digestion and absorption in the small intestines; however, such fibers are susceptible to varying degrees of microbial fermentation or degradation in the colon. Such degradation results in the production of carbon dioxide, hydrogen, methane, and various short chain fatty acids.

For much of the twentieth century the common notion among clinicians and nutritionists was that fiber was roughage or the like comprised of indigestible cell walls. Except for providing bulk for normal bowel function, such fiber was considered to be of no nutritional value. Accordingly, many food scientists directed their efforts toward enhancing the purity of food by removing dietary fiber.

However, during the last few decades, stimulated principally by epidemiological observations revealing differences in disease patterns between populations, researchers began to accumulated a large body of evidence linking a low fiber western diet with the incidence of numerous chronic diseases. Numerous laboratory and clinical investigations have also confirmed various risk factors associated with low fiber diets and the protective nature of high fiber diets.

The association of high dietary fiber intake with lower risk or improvement in several chronic diseases has led to recommendations to increase dietary fiber consumption to 20-35 grams per day. Because of these recommendations and the mounting recognition of health benefits of high fiber diets, health care professionals have aggressively attempted to encourage individuals to consume high fiber diets that are rich in fruits, vegetables,

legumes and whole grains. Regrettably, many of the most popular foods, and particularly those most popular in western diets, are low in dietary fiber. Thus, for those consuming an affluent "refined western diet", satisfying these recommendations is a difficult task. Accordingly, despite the recommendations
5 advocating high fiber diets, the intake of dietary fiber has not significantly increased. Recent consumption surveys reveal that average dietary intake of fiber remains at approximately 10-12 grams per day.

As a result, a variety of dietary fiber supplements have been marketed for increasing the consumption of dietary fiber. Unfortunately,
10 however, such supplements have achieved limited consumer acceptance. Much of the dissatisfaction arises because of the physical organoleptic and other characteristics of the fiber components which make up the great majority of dietary fiber supplements currently available. Common dietary fiber supplements are comprised of fiber components such as psyllium (sold under the
15 trademark Metamucil or Fiberall), methylcellulose (sold under the trademark Citrucel) and polycarbophil or calcium polycarbophil (sold under the trademark Fiber Con). These generally have a significant affinity for water. Thus, when exposed to water or other fluids prior to or during ingestion, or when progressing through the digestive system, these components tend to swell quickly and
20 produce highly viscous fluids and gels. For instance, when hydrated, psyllium fiber produces an unacceptably gummy, chewy product. This has led directly to increased safety risk such as choking, obstruction and the like, both during and after ingestion. In fact, scientific literature has reported obstructions (esophageal

and small bowel) requiring medical attention from the consumption of both insoluble and soluble fiber supplements.

To minimize this problem, it is recommended that present fiber supplements be ingested while consuming a large quantity of liquids (a
5 minimum of eight ounces of fluid) or that smaller quantities of the supplement be ingested. In fact, the FDA's Tentative Final Monograph for Laxatives specifies that a full glass (8 ounces) of liquid be taken with each dose of certain fiber supplements. Typically, dietary fiber supplements are ingested in the form of swallowable tablets, reconstitutable powders or wafers. Swallowable tablets,
10 because of the above safety concerns, are limited to tablets of one gram or less and more typically 0.5 grams or less. This, however, leads to two areas of consumer dissatisfaction: the need to ingest a large amount of liquid per dose as well the need for a large number of doses to get a meaningful amount of fiber.

Fiber supplements in the form of a reconstitutable powder have also
15 met with limited consumer acceptance due principally to mouth feel of the product (the texture and grittiness), gelling due to viscosity buildup, visual appearance, the relatively large amounts of liquid required for mixing and consumption and limited palatability. The inconvenience of reconstituting and ingesting the product outside the home and the necessity for cleanup also
20 encumbers lifestyle and results in poor compliance. As an alternative, fibers supplements are often offered as wafers or as swallowable tablets as described above.

To overcome some of the problems identified above, the prior art teaches the encapsulation or pre-coating of dietary fiber supplements delivered as

swallowable tablets. Although this somewhat improves certain of the organoleptic properties by masking undesirable flavors and texture and delays hydration until it passes through the oral cavity, the limitations resulting from the relatively small swallowable tablets continue to exist. The prior art also

5 describes attempts to mask the fibrous mouth feel of current fiber supplements by concealing the dietary fiber in wafers, baked goods, granola-type products, power bars, cookies, cereals and snack foods. While this technology has achieved some degree of success, it often requires the inclusion of ingredients high in fat, carbohydrates and calories and low in dietary fiber. Thus, consumers wishing to

10 restrict their caloric intake are often reluctant to utilize such products. Further, the level of dietary fiber that can be incorporated into other foods without adversely affecting the taste and mouth feel is quite limited. In general, the upper limit is about 5% by weight.

Still further, the prior art teaches the use of fine powders of dietary

15 fibers, excipient and or dispersing agents to reduce the formation of fibrous clumps or "fish eyes" during rehydration. In comparison to coarser powders, the fine powders of dietary fibers tend to be less gritty upon reconstitution.

According, there is a need for a dietary fiber supplement which addresses the problems in the prior art and provides a dietary fiber supplement

20 and a delivery system for a dietary fiber which does not pose safety concerns resulting from viscosity buildup or gelling and which is palatable, aesthetically pleasing and exhibits characteristics which enable it to be delivered as a chewable tablet or lozenge without the choking, obstruction or other safety concerns.

SUMMARY OF THE INVENTION

In contrast to the prior art, the present invention provides a dietary fiber supplement, and more particularly, a dietary fiber supplement delivery system which enables relatively large doses of fiber to be ingested with

5 dissolution and substantial hydration in the oral cavity without experiencing safety concerns and while providing a palatable and organoleptically pleasing product. More specifically, the present invention relates to the discovery of a subset of soluble dietary fibers which do not significantly increase in viscosity or gel when exposed to water or other liquids, yet possess the desirable organoleptic

10 characteristics and the ability to function as a dietary fiber. This particular subset of soluble dietary fibers exhibits characteristics which enable the same to be delivered as a chewable tablet, wafer or lozenge having excellent texture, mouth feel and palatability and which can be delivered without experiencing the choking, obstruction or other safety concerns commonly associated with dietary

15 fiber supplements currently existing in the art. The dietary fiber supplement of the present invention is designed to be chewed or dissolved slowly and then swallowed without experiencing such safety concerns or unpleasant organoleptic or other properties.

Further, the dietary fiber supplement of the present invention is

20 organoleptically pleasing and does not require the addition of masking agents or coating techniques to improve its taste and mouth feel. Further, it does not require delaying hydration until it passes out of the oral cavity as is required with some present supplements. Accordingly, this subset of materials results in improved consumer acceptance and compliance. This in turn encourages and

enables the long term consumption of fiber supplements for those individuals who will benefit from such increase in fiber intake.

Preferably the dietary fiber supplement in accordance with the present invention is comprised of a subset or category of fiber supplements

5 which, when exposed to water or other fluid, do not result in significant buildup of viscosity or gelling. These fiber components are sometimes referred to herein as "non-gelling low viscosity fiber components" or simply as "low viscosity fiber components". More specifically, the category of materials that are applicable to the present invention are those materials which when exposed to water or other

10 liquid result in a solution which does not gel and exhibits a viscosity significantly less than the viscosity of similar solutions of currently available dietary fiber supplements. Such materials also preferably exhibit organoleptically pleasing properties and palatability. Although a variety of dietary fiber components may exhibit these properties, the preferred embodiment contemplates a dietary fiber

15 component comprised of inulin or fructooligosaccharides (FOS) either individually or in combination. In accordance with the present invention, such component is delivered in a chewable form as a chewable tablet, lozenge, wafer, cookie or the like (hereinafter referred to as a "chewable tablet") ranging in size from one-half gram to as much as ten grams. Preferably the chewable tablet

20 comprises at least 10% by weight of the dietary fiber component, more preferably, at least 30% by weight and most preferably at least 50% by weight.

The present invention also relates to a dietary fiber delivery method for a human subject which involves preparing a chewable tablet or wafer of the

type described above and then chewing and swallowing the tablet. This may be accomplished with or without water.

Most significantly, the present invention provides a delivery system for fiber supplementation in a chewable form which can deliver large quantities of fiber, particularly in the range of 3-5 grams, in a single chewable tablet which unexpectedly is quite palatable and demonstrates a high degree of consumer acceptability. Notwithstanding the size of the chewable tablet or wafer, it provides a pleasing mouth feel which dissolves rapidly due to the presence of the soluble fiber used in this invention. The present invention thus avoids the unpleasant gritty or gummy textures associated with chewable fiber supplements of the prior art.

Accordingly, it is an object of the present invention to provide a novel, safe, advantageous, user friendly, convenient, highly acceptable mechanism for the delivery of dietary fibers in a form and in quantities previously unavailable.

Another object is to provide a chewable delivery system comprised of one or more soluble dietary fibers which are to be masticated (or slowly dissolved) in the oral cavity with substantial hydration and swallowed upon complete disintegration without experiencing the safety concerns and unpleasant organoleptic properties of presently available fiber supplements.

Another object of the present invention is to provide a chewable tablet for the administration of physiologically active soluble fibers or resistant starches while avoiding the safety concerns and other consumer disadvantages associated with such fibers.

Another object of the present invention is to provide a delivery system for a dietary fiber supplement which does not gel and which encourages long-term compliance and consumption.

A still further object of the present invention is to provide a dietary
5 fiber supplement in a form which exhibits a relatively low viscosity when exposed to water or other liquids.

These and other objects of the present invention will become apparent with reference to the description of the preferred embodiment.

10 DESCRIPTION OF THE PREFERRED EMBODIMENT

Because of the association between high dietary fiber intake and improved health benefits, the general consensus and recommendations from health care professionals is to increase the consumption of dietary fiber. Because many diets, and in particular affluent western diets, fail to provide sufficient fiber
15 intake, fiber supplements are highly recommended. Depending upon the particular individual's medical and health status and diet, it is anticipated that the adult daily fiber supplement could range from 1-20 grams and more probably from 3-15 grams. Presently available fiber supplements are generally administered from 1-6 times per day in unit dosages of 0.5-3 grams.

20 In accordance with the present invention, a dietary fiber supplement delivery system is provided in which dramatically increased quantities of fiber supplements can be administered and ingested without danger of choking, internal obstruction or other safety concerns. Preferably, the system includes a chewable tablet comprised principally of a low viscosity dietary fiber

component which when exposed to water or other liquid exhibits a relatively low viscosity (hereinafter sometimes referred to as "low viscosity fiber component"), but which still functions as a dietary fiber and provides highly desirable organoleptic and other properties.

5 The low viscosity fiber components useful in the present invention are those dietary fiber components which exhibit relatively low viscosity buildup when exposed to water or other fluids. More specifically, the dietary fiber components exhibiting the reduced viscosity property of the present invention are those fiber components which when combined with water to form a 10% by
10 weight solution of the component exhibit a viscosity at 25°C which is preferably less than 100 centipoise (cps), more preferably less than 25 cps and most preferably less than 5 cps.

 Although it is contemplated that a variety of fiber components would meet this low viscosity requirement, the preferred embodiment contemplates
15 that such component would be either inulin or a fructooligosaccharide (FOS). Inulin or FOS can be provided either individually or in combination and is preferably delivered as a chewable tablet. It can also be provided as a powder to be reconstituted with water, if desired. Inulin is comprised of fructofuranose polymers (oligomer and polymers of fructose) of varying chain lengths with a DP
20 (degree of polymerization) ranging from 2 to 60 monomeric fructose units linked to a terminal glucose molecule. More preferably, inulin of the present invention has a DP of 2-20 and mostly preferably a DP of less than 10. FOS is a mixture of the smaller fructan polymer fractions with a DP of 2 to 8. Thus, the molecules of FOS have 2 to 8 fructose units linked to a terminal glucose molecule. FOS can be

commercially produced by the partial enzymatic hydrolysis of inulin or enzymatically synthesized from sucrose. Inulin or FOS offer functional physical and organoleptic advantages over other nondigestible polysaccharides which make up what are currently considered as dietary fibers or resistant starches.

- 5 These functional, organoleptic and aesthetic properties provide significant advantages to the present invention which do not exist with respect to present dietary fiber supplements. In contrast to currently available fiber supplements, inulin and FOS comprise relatively small polymers which at anticipated levels of fiber do not build viscosity, swell or gel. Additionally, inulin and FOS are
- 10 slightly sweet and have a pleasing taste and texture.

The inulin material used in the practice of this invention may be obtained from a variety of commercially available sources. Economically obtainable amounts are found in a series of plants, such as Jerusalem artichoke tubers and dahlia tubers, and also in chicory roots. It is known to obtain inulin

15 from these sources by hot water extraction and drying, see U.S. Patent 5,478,732. Inulin can also be prepared by pressing processes known in the art such as are shown in U.S. Patent No. 5,422,346.

The non-gelling and reduced viscosity property of the inulin, FOS and other dietary fiber components applicable to the present invention is to some

20 extent directly related to the molecule size and thus the molecular weight of the particular polysaccharide. Inulin is a mixture of fructose polymers of varying chain lengths ranging from 2 to 60 monomers with a molecular weight of less than 11,000 and with a typical molecular weight of about 5,000.

Fructooligosaccharides with chain lengths ranging from 2 to 8 fructose

monomers have a molecular weight of less than about 1,500. The molecular weight of currently available dietary fibers typically exceed 100,000. For example, the molecular weight of guar is greater than 200,000, the molecular weight of tragacanth exceeds 800,000, and the molecular weight of pectin ranges from 40,000 to 400,000. The molecular weight of the low viscosity fiber component molecules in accordance with the present invention is preferably less than 40,000, more preferably less than 25,000 and most preferably less than about 5,000.

During hydration, a gram of either inulin or FOS binds less than two grams of water. In contrast, conventional dietary fiber components bind significant quantities of water. For example, one gram of xanthin will bind approximately 18.5 grams of water, one gram of carrageenan will bind approximately 32.9 grams of water, one gram of guar will bind approximately 24.9 grams of water, one gram of pectin will bind between 5 to 56.2 grams of water and one gram of karaya will bind approximately 12.5 grams of water. Accordingly, the water binding property of the low viscosity fiber component in accordance with the present invention is that one gram of the fiber component will preferably bind less than 10 grams of water, more preferably less than 5 grams of water and most preferable less than 3 grams of water.

Both the molecular weight property and the water absorbing capacity of a dietary fiber component are further related to the ability of that component to form a viscous solution when exposed to water. Typically, a 2% by weight H_2O solution of tragacanth exhibits a viscosity of approximately 1,000 cps, a 2% by weight H_2O solution of guar exhibits viscosity of about 25,000 cps, a 2% by

- weight H₂O solution of karaya exhibits a viscosity of approximately 8,000 cps and a 2% by weight H₂O solution of xanthin exhibits a viscosity of about 4,000 cps. In comparison, even a 10% by weight H₂O solution of inulin and FOS exhibit relatively low viscosities on the order of about 2 cps. This is to be further
- 5 compared with 10% by weight H₂O solutions of native dietary fiber such as gum arabic, which exhibits a viscosity of about 20 cps, and arabinogalactan, which exhibits a viscosity of about 3 cps. Although arabic is a relatively large molecule with a molecular weight of up to 600,000, it is a globular rather than a linear molecule which resists hydration and thus exhibits a relatively low viscosity.
- 10 The low viscosity fiber component in accordance with the present invention preferably comprises a component which when combined with water to form a 10% by weight H₂O solution of such component exhibits a viscosity at 25°C of preferably less than 100, more preferably less than 25, and most preferably less than 5 cps.
- 15 The discussion of the preferred embodiment has been with respect to inulin and FOS which exhibit the desired properties of reduced viscosity in their natural, unprocessed form. However, the present invention also contemplates that various existing high molecular weight, nondigestible polysaccharides currently available as dietary fiber supplements may be processed
- 20 to reduce their viscosity, gelling and other undesirable properties, and thus function in accordance with the present invention. Two examples are guar and various resistant starches.

Guar is a high molecular weight polysaccharide which at low concentrations forms viscous solution and gels. Prior art has shown, however, that through controlled hydrolysis, the average molecular weight of guar can be significantly reduced. This reduction in polymer size can significantly alter it

5 viscosity building and gelling characteristics. For example, it is known that Taiyo Kagaku Co., Ltd produces a hydrolyzed guar through controlled enzymatic hydrolysis which produces an average molecular weight guar approximately one tenth that of the starting material. This hydrolysis improves the organoleptic properties of the resulting material and significantly reduces the viscosity and

10 gelling characteristics. The viscosity of a solution of this hydrolyzed guar may be as much as 2,000 times or more lower than a similar solution of the native guar. Accordingly, it is contemplated that the low viscosity fiber component of the present invention, in addition to comprising inulin or FOS, may also comprise nondigestible polysaccharides which have been hydrolyzed or otherwise

15 processed to reduce the viscosity of a solution of such material in accordance with the levels specified above.

Starch is a plant's storage form for glucose. Native dietary starch is a complex carbohydrate consisting of either straight (amylose: alpha-1,4 glucosidic bonds) or branched (amylopectin: alpha-1,4 and alpha-1,6 glucosidic bonds) chain

20 monomers of glucose. For most of these complex polysaccharides, enzymatic hydrolysis occurs in the mouth, stomach and small intestines when ingested. Resistant starch is that fraction of dietary starch that escapes hydrolysis and enters the colon where it is subject to fermentation by the colonic flora. Accordingly, resistant starches are polysaccharides which are not digested by the human

enzymes within the oral cavity and the gastrointestinal tract and thus are considered to be dietary fiber. Accordingly, it is contemplated that the non-gelling and low viscosity fiber component in accordance with the present invention may comprise resistant starches to the extent that the viscosity and
5 other requirements described above are met.

Accordingly, the principle component of the dietary fiber supplement in accordance with the present invention is a non-gelling, low viscosity fiber component most commonly comprising a polysaccharide or complex carbohydrate exhibiting the properties described above.

10 One of the novel delivery forms of such low viscosity fiber component is in a chewable form such as a chewable tablet which is capable of delivering supplemental quantities of dietary fibers from 0.5 to as much as 6.0 grams or more per dose. Preferably, the chewable tablet in accordance with the present invention is greater than 0.5 grams, more preferably greater than one
15 gram and most preferably greater than two grams.

The manufacture of chewable tablets in accordance with the present invention utilizes tableting procedures and practices commonly known in the art and employed to produce tablets. Accordingly, the process of producing the chewable tablets in accordance with the present invention follows procedures
20 known in the art. Further, except for the selection of the appropriate low viscosity fiber component, the formulation may be widely varied to attain the product attributes (flavor, aroma, color, texture and physical characteristics) and provide for appropriate and desired delivery of nutrients.

In general, the chewable tablet in accordance with the present invention is prepared by the dry blending of the desired ingredients to assure homogeneity in an appropriate blender (V, ribbon, paddle or plow), followed by compressing the mixture into a tablet possessing the preferred physical characteristics. To insure a final tablet of proper chewable consistency and/or facilitate tablet dissolution, etc., excipients such as microcrystalline cellulose, sugar alcohol (sorbitol, mannitol, xylitol) and sugars (glucose, fructose, sucrose) may be added either individually or in combination in any desired ratio. Further, to increase the nutritional value of the chewable tablet, the addition of various vitamins and/or minerals or combinations thereof may be included. These additives can increase the utility of the fiber supplement and be a particularly convenient mechanism for addressing a particular individual's nutritional needs. Still, further, to assure taste acceptability of the tablet, flavor additives, either individually or in combination, may be included. To improve the aesthetics of the tablets, the inclusion of coloring agents in any desired ratio may be used. Lubricants/release agents such as stearic acid, magnesium stearate or polyethylene glycol may also be included either individually or in combination to facilitate tablet ejection from the mold.

The tablet of the present invention can also include calcium so as to achieve the known benefits of the combination of calcium and dietary fiber.

Although it is contemplated that the chewable tablet in accordance with the present invention can be comprised almost exclusively (i.e. up to 99% or 100%) of the low viscosity fiber component, it is more likely that one or more of the above or other additives may be included to meet a particular nutritional,

organoleptic or other goal. Accordingly, it is contemplated that the chewable tablet in accordance with the present invention will be comprised of at least about 10% by weight of the low viscosity component. More preferably, the chewable tablet is intended to comprise at least 30% by weight up to at least 50%
5 by weight of the low viscosity component. Most preferably, the tablet comprises 30% to 60% by weight of the low viscosity fiber component.

The present invention further relates to methods of reducing serum cholesterol in humans. These methods comprise orally administering to a human in need of cholesterol reduction a safe and effective amount of a
10 chewable tablet of the present invention. Preferably, the tablets are administered in 3-5 gram tablets 3-4 times daily.

In addition to providing the low viscosity fiber component as a chewable tablet, it is also contemplated that the low viscosity fiber component may be administered in powder form to be added with water or other fluid and
15 reconstituted prior to ingestion.

Having described the details of the low viscosity fiber component and its administration in the form of a chewable tablet, the following examples demonstrate the present invention. All ingredient percentages refer to a measurement by weight.

20

Example 1 - Chewable Dietary Fiber Supplement

Chewable tablets as a delivery system were prepared in the manner described above. The following example demonstrates a sugar free chewable tablet formulated with inulin as the chewable matrix.

Ingredient	Percentage
Inulin	0.9901
Mg Stearate	0.0099

- Ingredients are dry mixed in an appropriate blender (V, ribbon, paddle, and plow)
- 5 to assure homogeneity of the batch and then compressed into tablets. This mixture when compressed into tablets had a pleasant, slightly sweet taste. The chewiness which is a function of the rate of hydration in the oral cavity can be somewhat controlled by the compression pressure. The shape, size, and weight of the tablet will vary to reflect the desired amount of fiber to be delivered.
- 10 Above 10 grams the size may become overwhelming and the preferred shape may be cubular for these supplements with such large quantities of dietary fibers.

Example 2 - Chewable Tablet Formulated with Inulin

- Chewable tablets as a delivery system were prepared in the manner
- 15 described above. The following example demonstrates a sugar free chewable tablet formulated with inulin as the chewable matrix.

	Ingredient	Percentage
	Inulin	0.5935
	Sorbitol	0.3956
20	Mg Stearate	0.0059
	Spearmint flavor	0.0050

Ingredients are dry mixed in an appropriate blender (V, ribbon, paddle, and plow) to assure homogeneity of the batch and then compressed into tablets of appropriate size for the deliver of desired quantity of dietary fiber. A 5.055 gram

tablet has been found to be a particularly pleasant way of delivering 3 grams of inulin.

Example 3 - Chewable Tablet - Formulated with FOS

5 Chewable tablets as a delivery system were prepared in the manner described above. The following example demonstrates a sugar free chewable tablet formulated with FOS as the chewable matrix.

	Ingredient	Percentage
	FOS	0.5935
10	Sorbitol	0.3956
	Mg Stearate	0.0059
	Orange flavor	0.0050

Ingredients are dry mixed in an appropriate blender (V, ribbon, paddle, and plow) to assure homogeneity of the batch and then compressed into tablets of
15 appropriate size for the delivery of desired quantity of dietary fiber.

Example 4 - Chewable Tablet -Inulin & FOS

Chewable tablets as a delivery system were prepared in the manner described above. The following example demonstrates a sugar free chewable tablet formulated with a mixture of inulin and FOS as the chewable matrix.

5	Ingredient	Percentage
	Inulin	0.2967
	FOS	0.2967
	Sorbitol	0.3956
	Mg Stearate	0.0060
10	Orange favor	1.0000

Ingredients are dry mixed in an appropriate blender (V, ribbon, paddle, and plow) to assure homogeneity of the batch and then compressed into tablets of appropriate size for the delivery of desired quantity of dietary fiber.

Example 5 - Chewable Tablet - Vitamin & Mineral Fortified

The inclusion of vitamins and/or minerals either singly or in combination as a value added feature for chewable fiber tablets as a delivery systems for soluble dietary fiber or resistant starches. The tablets were prepared in the manner described above. The following example demonstrates a sugar-free, nutrient fortified chewable tablet.

Ingredient	Percentage
Inulin	0.5935
Sorbitol	0.2967
Mineral Premix	0.0692

Vitamin Premix	0.0297
Mg Stearate	0.0059
Spearmint flavor	0.0050

Ingredients are dry blended and then compressed into tablets of appropriate size
5 and shape.

Example 6 - Chewable Tablet - Calcium Fortified

Chewable tablets as a delivery system were prepared in the manner
described above. The following example demonstrates a sugar free chewable fiber
10 tablet with the inclusion of a Calcium.

	Ingredient	Percentage
	Inulin	0.5935
	Sorbitol	0.1978
15	Calcium Carbonate	0.1978
	Calcium lactate	
	Calcium gluconate,etc.	
	Mg Stearate	0.0059
	Butterscotch flavor	0.0050

20 Ingredients are dry blended and then compressed into tablets of appropriate
weight and size. A 3.16 gram tablet of the above blend has been found to be a
particular pleasant way of delivering 250 mg of calcium and 1.875 grams of
inulin.

25

Example 7 - Chewable Tablet -

with added Bovine Immunoglobulin Concentrate (BIC)

The therapeutic value of the chewable fiber to the user tablet can be improved by the inclusion of biologics. Chewable fiber tablets as a delivery systems for bovine immunoglobulins were prepared in the manner described above. The following example demonstrates one such chewable tablet.

5	Ingredient	Percentage
	Inulin	0.4926
	Sorbitol	0.3284
	BIC	0.1642
	Mg Stearate	0.0098
10	Amaretto flavor	0.0048

Ingredients are dry blended and then compressed into tablets of appropriate size and weight.

The chewable dietary fiber supplement can be used to deliver specific bovine antibodies to control the microbial flora in the oral cavity, stomach, small intestines, and colon. As such a chewable dietary fiber tablet with added bovine immunoglobulin can be used to reduce the occurrence of certain health concerns associated with microbial growth or as the therapy to treat these concerns.

The inclusion of other biologics is also contemplated. The chewable dietary fiber supplement provides a logical delivery system for a probiotic microbial mixture. The fermentable dietary fibers act as an enhancer of the probiotics cultures.

Example 8 - Chewable Tablet - Sugar-free

Chewable tablets as a delivery system were prepared in the manner described above. The following example demonstrates a sugar free chewable tablet.

5	Ingredient	Percentage
	Inulin	0.7913
	Sorbitol	0.1978
	Mg Stearate	0.0059
	Orange cream flavor	0.0050

- 10 Ingredients are dry blended and then compressed appropriate sized tablets. This mixture provides a particularly pleasant way of providing inulin in quantities between 500 mg and 8 grams.

Example 9 - Chewable Tablet - Containing Sugar

- 15 Chewable tablets as a delivery system were prepared in the manner described above. The following example demonstrates a sugar containing chewable tablet.

	Ingredient	Percentage
	Inulin	0.7913
	Fructose	0.1978
	Mg Stearate	0.0059
5	Orange cream flavor	1.0050

Ingredients are dry blended and then compressed into appropriate sized tablets.

This mixture provides a particularly pleasant way of providing inulin in quantities between 500 mg and 8 grams.

Although the description of the preferred embodiment has been
10 quite specific, it is contemplated that various modifications could be made without deviating from the spirit of the present invention. Accordingly, it is intended that the scope of the present invention be dictated by the appended claims rather than by the description of the preferred embodiment.

CLAIMS

1. A delivery system for a dietary fiber supplement comprising:
a chewable tablet or wafer comprised of at least 10% by weight
of a water soluble fiber which fiber, when combined with water to
5 form a 10% by weight solution of said water soluble fiber, exhibits a
viscosity at 25°C of less than 100 centipoise.
2. The delivery system of claim 1 wherein said water soluble fiber is
present in the amount of at least 30% by weight.
- 10 3. The delivery system of claim 2 wherein said water soluble fiber is
present in the amount of at least 50% by weight.
4. The delivery system of claim 1 wherein said water soluble fiber
15 exhibits a viscosity less than 25 centipoise.
5. The delivery system of claim 4 wherein said water soluble fiber
exhibits a viscosity less than 5 centipoise.
- 20 6. The delivery system of claim 1 wherein said chewable tablet or
wafer has a weight of at least 0.5 grams.
7. The delivery system of claim 6 wherein said chewable tablet or
wafer has a weight of at least 1.0 gram.
- 25 8. The delivery system of claim 7 wherein said chewable tablet or
wafer has a weight of at least 2.0 grams.

9. The delivery system of claim 1 wherein said water soluble fiber is one of, or a mixture of, inulin and a fructooligosaccharide.
10. The delivery system of claim 9 wherein said water soluble fiber is
5 inulin.
11. A method of delivering a dietary fiber supplement to a human subject comprising the steps of:
- preparing a chewable tablet or wafer comprised of at least 10%
10 by weight of a water soluble fiber which fiber, when combined with water to form a 10% by weight solution of said water soluble fiber, exhibits a viscosity at 25°C of less than 100 centipoise, and
chewing and swallowing said tablet or wafer.
- 15 12. The method of claim 11 wherein said water soluble fiber is present in the amount of at least 50% by weight.
13. The method of claim 12 wherein said water soluble fiber exhibits a viscosity less than 5 centipoise.
- 20 14. The method of claim 13 wherein said chewable tablet or wafer has a weight of at least 1.0 gram.
15. The method of claim 14 wherein said water soluble fiber is one of,
25 or a mixture of, inulin and a fructooligosaccharide.
16. The method of claim 15 wherein said water soluble fiber is inulin.

17. The method of claim 11 wherein said water soluble fiber is one of, or a mixture of, inulin and a fructooligosaccharide.

18. The method of claim 17 wherein said water soluble fiber is inulin.

5

19. A chewable tablet or wafer formulation of a non-gelling, low viscosity dietary fiber supplement comprising about 30% to 100% by weight of a water soluble fiber selected from inulin and fructooligosaccharides.

10 20. The tablet or wafer formulation of claim 19 wherein the inulin has a DP ranging from 2 to 60.

21. The tablet or wafer formulation of claim 19 wherein the fructooligosaccharides comprise FOS having a DP ranging from 2 to 8.

15

22. The tablet or wafer formulation of claim 19 wherein said water soluble fiber is present in the amount of at least 30% by weight.

23. The tablet or wafer formulation of claim 19 wherein said water soluble
20 fiber is present in the amount of at least 50% by weight.

24. The tablet or wafer formulation of claim 19 wherein said water soluble fiber when combined with water, forms a 10% by weight solution and exhibits a viscosity at 25° C of less than 25 centipoise.

25

25. The tablet or wafer formulation of claim 19 wherein said water soluble fiber when combined with water, forms a 10% by weight solution and exhibits a viscosity at 25° C of less than 5 centipoise.

5

26. The tablet or wafer formulation of claim 19 wherein said chewable tablet or wafer has a weight of at least 0.5 grams.

10 27. The tablet or wafer formulation of claim 26 wherein said chewable tablet or wafer has a weight of at least 1.0 gram.

28. The tablet or wafer formulation of claim 27 wherein said chewable tablet
15 or wafer has a weight of at least 2.0 grams.

29. The tablet or wafer formulation of claim 19 further comprising added nutrients.

20 30. The tablet or wafer formulation of claim 19 further comprising added biologics.

31. A chewable table or wafer comprising a low viscosity dietary fiber component which, when combined with water, forms a 10% by weight solution
25 and exhibits a viscosity at 25° C of less than 100 centipoise.

32. The chewable table or wafer of claim 31 wherein said water soluble fiber is present in the amount of at least 30% by weight.

33. The chewable table or wafer of claim 32 wherein said water soluble fiber is
5 present in the amount of at least 50% by weight.

34. The chewable table or wafer of claim 31 wherein said water soluble fiber exhibits a viscosity less than 25 centipoise.

10

35. The chewable table or wafer of claim 34 wherein said water soluble fiber exhibits a viscosity less than 5 centipoise.

15

36. The chewable table or wafer of claim 31 wherein said chewable tablet or wafer has a weight of at least 0.5 grams.

20 37. The chewable table or wafer of claim 36 wherein said chewable tablet or wafer has a weight of at least 1.0 gram.

38. The chewable table or wafer of claim 37 wherein said chewable tablet or
25 wafer has a weight of at least 2.0 grams.

39. The chewable table or wafer of claim 31 further comprising added nutrients.
40. The chewable table or wafer of claim 31 further comprising added
5 biologics.
41. A method of reducing cholesterol by orally administering a dietary fiber supplement to a human subject comprising the steps of:
preparing a chewable tablet or wafer of at least 10% by weight of a water soluble
10 fiber which fiber, when combined with water to form a 10% by weight solution of said water soluble fiber, exhibits a viscosity of 25° C of less than 100 centipoise, and
chewing and swallowing said tablet or wafer.
- 15 42. The method of claim 41 wherein said water soluble fiber is present in the amount of at least 50% by weight.
43. The method of claim 42 wherein said water soluble fiber exhibits a
20 viscosity less than 5 centipoise.
44. The method of claim 43 wherein said chewable tablet or wafer has a weight of at least 1.0 gram.

45. The method of claim 44 wherein said water soluble fiber is one of, or a mixture of, inulin and a fructooligosaccharide.

5 46. The method of claim 45 wherein said water soluble fiber is inulin.

47. The method of claim 41 wherein said water soluble fiber is one of, or a mixture of, inulin and a fructooligosaccharide.

10

48. The method of claim 47 wherein said water soluble fiber is inulin.

49. A chewable tablet or wafer formulation containing a non-gelling, low viscosity dietary fiber supplement comprising a water soluble fiber selected from
15 inulin and fructooligosaccharides in a percentage by weight effective to avoid choking when ingested by a human subject.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/20245

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61K 9/20, 31/715

US CL : 424/439, 441, 464

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/439, 441, 464

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y, P	US 5,550,113 A (MANN) 27 August 1996, column 2, line 40 through column 5.	1-40
Y	US 5,422,346 A (MITCHELL et al.) 06 June 1995, examples 9, 11, 13, 14.	41-49

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

29 MARCH 1997

Date of mailing of the international search report

10 APR 1997

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